



Post Authorisation Assessments

Seresto 1.25 g + 0.56 g, Collar for Cats

Vm 00879/3034

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| • | 21 February 2023 | Change in the re-test period of the active substance. |
| • | 13 February 2023 | Change in the re-test period of the active substance. |
| • | 22 September 2021 | Addition of a manufacturer of the active substance. |
| • | 26 March 2021 | Changes to the labelling and package leaflet. |
| • | 02 October 2020 | Change of MAH, from Bayer plc, 400 South Oak Way, Green Park, Reading, Berkshire, RG2 6AD to Elanco Europe Ltd., Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom. |
| • | 01 June 2020 | Replacement of an excipient with a comparable excipient. |
| • | 02 March 2020 | Changes in the SPC, Labelling or Package Leaflet of veterinary medicinal products intended to implement the outcome of a procedure concerning PSUR. |
| • | 14 January 2020 | Addition of a manufacturer of the active substance. |
| • | 09 September 2019 | Change to part of the (primary) packaging material not in contact with the finished product formulation. Change in the number of units in a pack outside the range of the currently approved pack sizes of the finished product. Change in the number of units in a pack outside the range of the currently approved pack sizes of the finished product. |
| • | 26 October 2018 | Change in the safety database of an existing pharmacovigilance system as described in the DDPS |
| • | 18 September 2018 | Change in distributor details from Bayer plc, Animal Health Division, Strawberry Hill, Newbury, Berkshire, RG14 1JA to Bayer plc, 400 South Oak Way, Green park, Reading, Berkshire, RG2 6AD. |
| • | 21 December 2017 | Change in the address of the marketing authorisation holder from Bayer plc, Animal Health Division, Bayer House, Strawberry Hill, Newbury, Berkshire, RG14 1JA to Bayer plc, 400 South Oak Way, Green Park, Reading, Berkshire RG2 6AD . |
| • | 15 June 2017 | Change to in-process tests or limits applied during the manufacture of the finished product. |
| • | 31 March 2017 | Change in the name of the manufacturer of the active substance. |
| • | 16 December 2016 | Increase in the shelf-life of the finished product as packaged for sale, from 4 to 5 years. |
| • | 08 June 2016 | Change(s) to a DDPS following the assessment of the same DDPS in relation to another medicinal product of |

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| | | the same MAH. |
| • | 08 June 2016 | Renewal – UK as CMS. |
| • | 13 May 2015 | Change in the name of the manufacture of the active substance. Minor change to the test procedure of the active substance. |
| • | 15 February 2015 | Addition of specification parameters. |
| • | 28 November 2014 | Assessment of revised product literature. |
| • | 14 May 2014 | To include new therapeutic indications into the SPC/packaging information of Seresto in relation to the prevention of the transmission of Feline Vector Borne Diseases in cats. |
| • | 16 April 2014 | Change to marketing authorisation holder in France only from Bayer Santé to Bayer Healthcare. |
| • | 07 February 2014 | Significant change to the SPC regarding claim for use. |
| • | 11 December 2013 | Extension of shelf of the product as packaged for sale from 30 months to 48 months. |
| • | 07 June 2013 | Changes to section 4.6 Adverse Reactions of the SPC. |